taltz® together™ (ixekizumab) injection

Drafting a Formulary Exception Request Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Taltz Together™ at 1-844-TALTZ-NOW (1-844-825-8966).

A formulary exception is a type of coverage determination. It is used when a drug is not included on a health plan's formulary or is subject to a National Drug Code (NDC) block.

This resource, **Drafting a Formulary Exception Request Letter**, provides information to healthcare providers (HCPs) when drafting such a letter. A checklist is included below on what to include in the letter. A sample letter is attached to this document and contains useful information that many health plans require to process the request. Typically, the patient's medical records and a Letter of Medical Necessity (LMN) are submitted with the letter. The Formulary Exception Request Letter may originate from the patient, HCP, or legal representative.* Both the prescribing HCP and patient should sign the letter.

Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting **Taltz® (ixekizumab) injection (80 mg/mL)**; otherwise, treatment may be delayed.†

FORMULARY EXCEPTION REQUEST LETTER CONSIDERATIONS

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's name, relationship to the requestor, National Provider Identifier (NPI) number, specialty, address, telephone number/fax number, and date of submission
- Record the patient's current diagnosis
- Provide a copy of the patient's records with the following details:
  - Patient's history, diagnosis and specific International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
  - Patient's recent history of infection(s), along with any allergies and existing comorbidities
- Supply a recent photo(s) of the impacted area(s), if applicable
- Document prior treatments and the dates when they were tried
  - Describe the rationale for why each treatment was discontinued
- List the main reasons for requesting a formulary exception for Taltz, including strength, frequency, expected length of therapy, quantity, days of supply, and route of administration
- Explain and attest to why the plan's preferred formulary agents are not appropriate for the patient (eg, medications have been or will be ineffective, not as effective, or cause adverse effects)
  - List dates of trial of preferred agents
- If this letter serves as an appeal, include the case number from the denial letter, a copy of the denial letter, and a response to the denial
- Include an LMN

*Please note for Medicare Part D subscribers: Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee's representative, or the enrollee's doctor or other prescriber can request a coverage determination, including a request for a tiering or formulary exception. A request for a coverage determination can be made orally or in writing. **An enrollee, the enrollee's representative, or the enrollee's prescriber may submit a written request for a coverage determination in any format.**

†Please note that the Centers for Medicare & Medicaid Services (CMS) has developed "REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION" model forms that are posted on its website. For more information, visit https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html.

Please see Important Safety Information on page 4 and click to access the Prescribing Information and Medication Guide. Please see Instructions for Use included with the device.

Lilly

Sample Formulary Exception Request Letter

A Formulary Exception Request Letter is used when **Taltz® (ixekizumab) injection (80 mg/mL)** is not included on a health plan's formulary or is subject to an NDC block. This step may require the HCP to submit an LMN with the Formulary Exception Request Letter.

HCPs can follow this format for patients who are **NOT** currently receiving treatment with Taltz.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]
[Case identification]

To whom it may concern:

My name is **[HCP's name]**, and I am a **[board-certified medical specialty] [NPI]**. I am writing to request a formulary exception for my patient,* **[patient's name]**, who is currently a member of **[name of health plan]**. The request is for Taltz (ixekizumab). Treatment with Taltz [dose, frequency] is medically appropriate and necessary for this patient, who has been diagnosed with **[moderate to severe plaque psoriasis OR active psoriatic arthritis]**, **[ICD code]**. Therefore, I am requesting that the plan removes any relevant NDC blocks, so Taltz can be made available to my patient as a preferred medication.

If this appeal has been previously denied by the plan, sample wording from page 3 of this document can be placed after the second sentence of this paragraph.

FOR PATIENTS DIAGNOSED WITH MODERATE TO SEVERE PLAQUE PSORIASIS

Patient's history, diagnosis, condition, and symptoms*:

____ % of BSA impacted

____ % of BSA involving only sensitive areas ____ List sensitive areas involved _____

____ Other (please list) _____

Please detail all past treatments, including phototherapy, topical therapy, and/or DMARDs (eg, MTX).

Past treatment(s)†	Start/stop dates	Reason(s) for discontinuing

FOR PATIENTS DIAGNOSED WITH ACTIVE PSORIATIC ARTHRITIS

Patient's history, diagnosis, condition, and symptoms*:

____ Check here to affirm that patient has been diagnosed with active psoriatic arthritis.

Please detail all past treatments, including any DMARDs (eg, MTX).

Past treatment(s)†	Start/stop dates	Reason(s) for discontinuing

Provide the information that is applicable to the primary diagnosis.

____ Indicate here, by adding a check mark, that the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient has any serious infections, please list them below.

Infection name and affected part(s) of body	Treatment type(s)	Treatment start/stop dates	Anticipated resolution date

____ Check here to affirm that patient will not be taking Taltz in combination with another biologic therapy.

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†Identify drug name, strength, dosage form, and therapeutic outcome.
BSA, body surface area; DMARD, disease-modifying antirheumatic drug; MTX, methotrexate

Sample Formulary Exception Request Letter

taltz® together™ (ixekizumab) injection

[Include the main reasons for requesting this formulary exception.]

A Letter of Medical Necessity and pertinent medical records are enclosed, which offer additional support for the formulary exception request for Taltz.

Please contact me, **[HCP's name]**, at **[HCP's telephone number]** for a peer-to-peer review. I would be pleased to speak to why a Taltz formulary exception is necessary for **[patient's name]**'s treatment of **[moderate to severe plaque psoriasis OR active psoriatic arthritis]**.

Sincerely,

_____ _____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]

Encl: Medical records, clinical trial information, photo(s), Letter of Medical Necessity

INFORMATION FOR PATIENTS WHO HAVE BEEN TREATED WITH TALTZ

HCPs can utilize the following language for patients who **HAVE** been treated with Taltz and have had treatment interruptions.

To whom it may concern:

My name is **[HCP's name]**, and I am a **[board-certified medical specialty] [(NPI)]**. I am writing to request a formulary exception for my patient,* **[patient's name]**, who is currently a member of **[name of health plan]**. The request is for Taltz (ixekizumab). The patient was receiving treatment with Taltz **[dose, frequency]**, which is medically appropriate and necessary for this patient, who has been diagnosed with **[moderate to severe plaque psoriasis OR active psoriatic arthritis]**, **[ICD code]**. However, Taltz is no longer included on your plan's formulary list. Therefore, I am requesting that the plan removes any relevant NDC blocks, so Taltz can be made available to my patient as a preferred medication.

If this appeal has been previously denied by the plan, sample wording from the following section can be placed after the second sentence of this paragraph.

[In this section, the HCP should describe the severity of moderate to severe plaque psoriasis OR active psoriatic arthritis symptoms at the time the patient was first treated with Taltz. The patient's corresponding medical records and progress notes must be included, and therapeutic outcomes should be noted.]

FORMULARY EXCEPTION APPEAL

If this Formulary Exception Request Letter is an appeal, sample copy should include the following:

This is a formulary exception appeal. I have included a copy of the original denial letter and medical notes in response to the denial.

For appeals,† include the following:

- A copy of the denial letter
- Medical notes, written by the prescribing physician, in response to the denial letter

*Include patient's medical records and supporting documentation, including clinical evaluation, scoring forms, and photos of affected areas.
†An external review board or hearing may apply in some situations.

Please see Important Safety Information on page 4 and click to access the Prescribing Information and Medication Guide. Please see Instructions for Use included with the device.

Indications and Usage for Taltz® (ixekizumab) injection (80 mg/mL)
Taltz is indicated for adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and for adults with active psoriatic arthritis.

Important Safety Information

CONTRAINDICATIONS
Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections
Taltz may increase the risk of infection. In clinical trials of patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of patients with psoriatic arthritis. Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Closely monitor patients receiving Taltz for signs and symptoms of active TB during and after treatment.

Hypersensitivity
Serious hypersensitivity reactions, including angioedema and urticaria (each ≤0.1%), occurred in the Taltz group in clinical trials. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use with Taltz. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease
During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease. Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis.

Immunizations
Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with Taltz.

ADVERSE REACTIONS
Most common adverse reactions (≥1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections. Overall, the safety profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please click to access the Prescribing Information and Medication Guide.
Please see Instructions for Use included with the device.

IX HCP ISI 01DEC2017

Sources: 1. Centers for Medicare & Medicaid Services. Part D enrollee grievances, coverage determinations, and appeals. In: *Prescription Drug Benefit Manual*. Baltimore, MD: Centers for Medicare & Medicaid Services; 2014. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip. Accessed October 31, 2017. **2.** Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; 2017.